

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Lasse LEINO et al.

Serial Number: 10/534,988

Group Art Unit: 1612

Filed: May 16, 2005

Examiner: Simmons, Chris E.

For: PHARMACEUTICAL COMPOSITION FOR INTRACELLULAR  
ACIDIFICATION WITH CIS-UROCANIC ACID

REQUEST FOR RECONSIDERATION

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

December 15, 2009

Sir:

In response to the Official Action mailed June 24, 2009, a Petition for a three month Extension of Time being filed herewith, please reconsider this application in view of the following remarks. Claims 16, 19-22 and 28 are pending.

The 35 U.S.C. § 102(b) rejection of claims 16, 19-22 and 28 over U.S. Patent No. 5,995,869 to Cormier et al. is traversed. A feature of the claimed method for treatment of a local inflammatory disease or disorder includes adjusting the pH of the composition to a pH range of 6.1 to 7.0.

Cormier et al. fails to disclose (or suggest) this feature of the claimed method. Instead, Cormier et al. makes pH adjustment dependent on the anionic or cationic nature of the specific drug to

be administered in combination with cis-urocanic acid (or a cis-urocanic analog) in its electrotransport delivery method. Thus, Cormier et al. teaches the pH of compositions containing a cationic drug and cis-urocanic acid should be less than 5 (Col. 6, line 64 to Col. 7, line 1). When the drug is anionic, Cormier et al. broadly teaches the pH of the composition should be "greater than 5" (Col. 7, lines 2-5).

Importantly, Cormier et al. does not disclose a composition having a pH within the claimed pH range of 6.1 to 7.0. Instead, the Cormier et al. examples disclose formulations having a pH of 5 (Example 2), pH 2-4 (Example 3), pH 8 (Example 4) and pH 7.5 (Example 5). One of ordinary skill in the art would understand that the pH range of the Cormier et al. formulations is at least pH 2-8.

Where, as here, the prior art discloses a range (pH 2-8) which overlaps the claimed range (pH 6.1-7.0), but fails to disclose a specific example falling within the claimed range, anticipation is not made out unless the claimed subject matter is disclosed in the reference with "sufficient specificity". See Atofina v. Great Lakes Chem. Corp., 441 F.3d 991, 999, 78 USPQ2d 1417, 1423 (Fed. Cir. 2006) where the court held that a reference's temperature

range of 100-500°C, preferably 150-350°C, did not describe the claimed range of 330-450°C with "sufficient specificity" to be anticipatory. See also MPEP § 2131.03.

Cormier et al. does not describe the claimed pH range with "sufficient specificity" to be anticipatory. First, Cormier et al. makes the formulation pH dependent on the pharmaceutical, not cis-urocanic acid or its analog. Thus, the pH of the Cormier et al. formulation may be acidic or basic, and the permissible range is at least 2-8 based on the disclosure of its examples. Second, pH is a logarithmic range. The claimed pH range is 6.1 to 7.0, which is much narrower than the pH 2-8 range taught by Cormier et al.

Finally, there is nothing within Cormier et al. which would motivate one of ordinary skill in the art to modify its disclosure by adjusting one of its formulations to a pH of 6.1 to 7.0.

Reconsideration and withdrawal of the anticipation rejection of claims 16, 19-22 and 28 over Cormier et al. are respectfully requested.

A Supplemental Information Disclosure Statement was filed with the Amendment filed April 1, 2009. The Examiner is requested to return a copy of the Form PTO-1449 marked to indicate consideration

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of the listed references together with the next Patent Office communication.

It is believed this application is in condition for allowance. Reconsideration and withdrawal of the anticipation rejection of claims 16, 19-22 and 28, and issuance of a Notice of Allowance directed to those claims, are earnestly requested. The Examiner is urged to telephone the undersigned should he believe any further action is required for allowance.

The extension of time fee is being paid electronically today. It is not believed any additional fee is required for entry and consideration of this Request for Reconsideration. Nevertheless, the Commissioner is authorized to charge Deposit Account No. 50-1258 in the amount of any such required fee.

Respectfully submitted,

/James C. Lydon/

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Enclosure:  
Petition for Extension of Time